

Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims

1. (Currently Amended) A pharmaceutical composition as a solid dosage form comprising desmopressin, or a pharmaceutically acceptable salt thereof, as a therapeutically active ingredient together with a pharmaceutically acceptable excipient, diluent or carrier, or mixture thereof, wherein the pharmaceutical composition is composed of a compressed granulate and contains lubricant in an amount of from 0.05 to ~~less than 0.50~~ 0.40 percent by weight of said pharmaceutical composition.
2. (Currently Amended) A pharmaceutical composition according to claim 1 which contains lubricant in an amount of from 0.10 to ~~less than 0.50~~ 0.30 percent by weight of said pharmaceutical composition.
3. (Currently Amended) A pharmaceutical composition according to claim 2 which contains lubricant in an amount of from 0.15 to 0.45, ~~preferably from 0.20 to 0.40, and more preferably from 0.25 to 0.30;~~ percent by weight of said pharmaceutical composition.
4. (Currently Amended) A pharmaceutical composition according to claim 1 which is ~~compressed~~ composed of a compressed granulate with an average size of at least 100 μm , ~~preferably in the range of from 100 μm to 2 mm, more preferably in the range of from 100 to 600 μm .~~
5. (Currently Amended) A pharmaceutical composition according to claim 4, wherein said granulate has a size distribution where at least 50%, ~~preferably from 50 to 90%,~~ by volume thereof consists of granulate particles with a size of at least 100 μm , ~~preferably in the range of from 100 μm to 2 mm, more preferably in the range of from 100 to 600 μm .~~
6. (Previously Presented) A pharmaceutical composition according to claim 1, wherein said lubricant is selected from a group consisting of stearic acid, salts or esters of

stearic acid, hydrogenated vegetable oils, magnesium oxide, polyethylene glycol, sodium lauryl sulphate and talc, and mixtures thereof.

7. (Original) A pharmaceutical composition according to claim 6, wherein said lubricant is selected from magnesium stearate, calcium stearate, zinc stearate, glyceryl palmitostearate and sodium stearyl fumarate, and mixtures thereof.

8. (Previously Presented) A pharmaceutical composition according to claim 1, wherein at least one of said excipient, diluent and carrier is a substance selected from a monosaccharide, disaccharide, oligosaccharide and a polysaccharide.

9. (Original) A pharmaceutical composition according to claim 8, wherein the said substance has an average particle size in the range of from 60 to 1 000 μm .

10. (Currently Amended) A pharmaceutical composition according to claim 9, wherein said average particle size is in the range of from 70 to 500 μm , ~~preferably from 75 to 350 μm , more preferably from 100 to 200 μm , and even more preferably from 120 to 180 μm .~~

11. (Currently Amended) A pharmaceutical composition according to claim 8, wherein said substance is a disaccharide, ~~preferably lactose, and more preferably lactose α -monohydrate.~~

12. (Currently Amended) A pharmaceutical composition according to claim 8, wherein said polysaccharide is a starch, ~~preferably potato starch.~~

13. (Previously Presented) A pharmaceutical composition according to claim 8, wherein both said disaccharide and polysaccharide are present.

14. (Currently Amended) A pharmaceutical composition according to claim 13, wherein the weight ratio between said disaccharide and polysaccharide is from 100:1 to 1:100, ~~preferably from 10:1 to 1:10, and more preferably from 2:1 to 1:2.~~

15. (Currently Amended) A pharmaceutical composition according to claim 1, wherein the total combined amount of said excipient, diluent and carrier is from 5 to 99; ~~preferably from 50 to 99,~~ percent by weight of the pharmaceutical composition.

16. (Currently Amended) A pharmaceutical composition according to claim 1, wherein said solid dosage form is a perorally available tablet that is optionally adapted for oromucosal, ~~preferably buccal and/or sublingual,~~ administration.

17. (Previously Presented) A pharmaceutical composition according to claim 1, which comprises desmopressin acetate in an amount of from 20 to 600 µg per unit of solid dosage form.

18. (Currently Amended) A pharmaceutical composition according to claim 1, wherein each unit of solid dosage form has a hardness of at least 49N (5 kp).

19. (Currently Amended) A method for the manufacturing of a pharmaceutical composition as a solid dosage form comprising desmopressin, or a pharmaceutically acceptable salt thereof, as a therapeutically active ingredient, wherein said method comprises the steps of:

- i) mixing desmopressin and an excipient, diluent or carrier, or mixture thereof, optionally in the presence of a wetting agent;
- ii) subjecting the resulting mixture to formation of a granulate, optionally in the presence of a wetting agent, suitable for compression into said solid dosage form;
- iii) optionally performing said mixing and/or formation of a granulate in the presence of at least one additive selected from a disintegrating agent, binder, flavoring agent, preservative, colorant and a mixture thereof;
- iv) optionally drying said granulate;

v) compressing said granulate into said solid dosage form,
wherein lubricant is introduced so that the resulting pharmaceutical composition contains lubricant in an amount of from 0.05 to ~~less than 0.50~~ 0.40 percent by weight of said pharmaceutical composition.

20. (Currently Amended) A method according to claim 19, wherein the pharmaceutical composition contains lubricant in an amount of from 0.10 to ~~less than 0.50~~ 0.30 percent by weight of said pharmaceutical composition.

21. (Currently Amended) A method according to claim 20, wherein the pharmaceutical composition contains lubricant in an amount of from 0.15 to 0.45, ~~preferably from 0.20 to 0.40, and more preferably from 0.25 to 0.30;~~ percent by weight of said pharmaceutical composition.

22. (Currently Amended) A method according to claim 19, wherein said resulting mixture is subjected to formation of a granulate with an average size of a least 100 μm ; ~~preferably in the range of from 100 μm to 2 mm, more preferably in the range of from 100 to 600 μm .~~

23. (Currently Amended) A method according to claim 22, wherein said formation of granulate provides a size distribution where at least 50%, ~~preferably from 50 to 90%;~~ by volume of said granulate consists of granulate particles with a size of at least 100 μm , ~~preferably in the range of from 100 μm to 2 mm, more preferably in the range of from 100 to 600 μm .~~

24. (Previously Presented) A method according to claim 19, wherein said lubricant is selected from a group consisting of stearic acid, salts or esters of stearic acid, hydrogenated vegetable oils, magnesium oxide, polyethylene glycol, sodium lauryl sulphate and talc, and mixtures thereof.

25. (Original) A method according to claim 24, wherein said lubricant is selected from magnesium stearate, calcium stearate, glyceryl palmitostearate, sodium stearyl fumarate and zinc stearate, and mixtures thereof.

26. (Previously Presented) A method according to claim 19, wherein at least one of said excipient, diluent and carrier is a substance selected from a monosaccharide, disaccharide, oligosaccharide and a polysaccharide.

27. (Original) A method according to claim 26, wherein said substance has an average particle size in the range of from 60 to 1 000 μm .

28. (Currently Amended) A method according to claim 27, wherein said average particle size is in the range of from 70 to 500 μm , ~~preferably from 75 to 350 μm , more preferably from 100 to 200 μm , and even more preferably from 120 to 180 μm .~~

29. (Currently Amended) A method according to claim 26, wherein said substance is a disaccharide, ~~preferably lactose, and more preferably lactose α -monohydrate.~~

30. (Currently Amended) A method according to claim 26, wherein said polysaccharide is a starch, ~~preferably potato starch.~~

31. (Currently Amended) A method according to claim 19, wherein said solid dosage form is a perorally available tablet that is optionally adapted for oromucosal, ~~preferably buccal and/or sublingual,~~ administration.

32. (Previously Presented) A method according to claim 19, wherein said steps of mixing and formation of a granulate are performed in a single integrated machinery that is adapted for such a combined process.

33. (Currently Amended) A method according to claim 19, wherein said wetting agent is selected from water and a mixture of water and an alcohol, ~~preferably ethanol.~~

34. (Previously Presented) A method according to claim 19, wherein both said disaccharide and polysaccharide are present in the mixing step.

35. (Currently Amended) A method according to claim 34, wherein the weight ratio between said disaccharide and polysaccharide is from 100:1 to 1:100, ~~preferably from 10:1 to 1:10, and more preferably from 2:1 to 1:2.~~

36. (Currently Amended) A method according to claim 19, wherein the total combined amount of said excipient, diluent and carrier is from 5 to 99, ~~preferably from 50 to 99,~~ percent by weight of the pharmaceutical composition.

37. (Previously Presented) A method according to claim 19, wherein desmopressin acetate is used and mixed with the excipient, diluent or carrier in an amount that provides from 20 to 600 μg of desmopressin acetate per unit of solid dosage form.

Claims 38-39 Canceled

40. (New) A pharmaceutical composition according to claim 4 wherein said granulate has an average size of from 100 to 600 μm .

41. (New) A pharmaceutical composition according to claim 5, wherein said granulate has a size distribution where from 50 to 90% by volume thereof consists of granulate particles with a size of at least 100 μm .

42. (New) A pharmaceutical composition according to claim 5, wherein said granulate has a size distribution where at least 50% by volume thereof consists of granulate particles with a size in the range of from 100 to 600 μm .

43. (New) A pharmaceutical composition according to claim 10, wherein said average particle size is in the range of from 100 to 200 μm .

44. (New) A pharmaceutical composition according to claim 10, wherein said average particle size is in the range of from 120 to 180 μm .

45. (New) A pharmaceutical composition according to claim 11, wherein said substance is lactose- α -monohydrate.

46. (New) A pharmaceutical composition according to claim 12, wherein said polysaccharide is a potato starch.

47. (New) A pharmaceutical composition according to claim 14, wherein the weight ratio between said disaccharide and polysaccharide is from 2:1 to 1:2.

48. (New) A pharmaceutical composition according to claim 15, wherein the total combined amount of said excipient, diluent and carrier is from 50 to 99 percent by weight of the pharmaceutical composition.

49. (New) A pharmaceutical composition according to claim 16, wherein said solid dosage form is a perorally available tablet that is optionally adapted for buccal and/or sublingual administration.

50. (New) A method according to claim 22, wherein said resulting mixture is subjected to formation of a granulate with an average size of a from 100 to 600 μm .

51. (New) A method according to claim 23, wherein said formation of granulate provides a size distribution where from 50 to 90% by volume of said granulate consists of granulate particles with a size of at least 100 μm .

52. (New) A method according to claim 23, wherein said formation of granulate provides a size distribution where at least 50% by volume of said granulate consists of granulate particles with a size in the range of from 100 to 600 μm .

53. (New) A method according to claim 28, wherein said average particle size is in the range of from 100 to 200 μm .

54. (New) A method according to claim 28, wherein said average particle size is in the range of from 120 to 180 μm .

55. (New) A method according to claim 29, wherein said substance is lactose- α -monohydrate.

56. (New) A method according to claim 30, wherein said polysaccharide is a potato starch.

57. (New) A method according to claim 31, wherein said solid dosage form is a perorally available tablet that is optionally adapted for buccal and/or sublingual administration.

58. (New) A method according to claim 33, wherein said alcohol is ethanol.

59. (New) A method according to claim 35, wherein the weight ratio between said disaccharide and polysaccharide is from 2:1 to 1:2.

60. (New) A method according to claim 19, wherein the total combined amount of said excipient, diluent and carrier is from 50 to 99 percent by weight of the pharmaceutical composition.